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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,450	12/05/2003	Christina Khoo	7129-00	1031

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EXAMINER

FORD, ALLISON M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/729,450	Applicant(s) KHOO ET AL.	
	Examiner Allison M Ford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1651

DETAILED ACTION

Status of Application

Claims 1-14 are pending in the current application.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: ANTI-DIARRHEA COMPOSITION CONTAINING GLUTAMINE.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 & 4-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 1 is directed to a composition suitable for mammalian oral ingestion in a mammal having GI tract inflammation comprising an anti-diarrhea effective amount of glutamine, fermentable fiber(s), antioxidant(s), and omega-3 fatty acid(s). It is unclear what amount comprises an effective amount of the listed ingredients.

Applicant's claims 4-13 use the notation "wt %" to describe the percent by weight the respective ingredients are present in the composition. It would be more appropriate and clear to say "percent by weight" or "% (w/w)" or "% by wt."

Art Unit: 1651

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7, & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Shields, Jr. et al (US Patent 6,156,355).

Applicant's claim 1 is directed to a composition suitable for mammalian ingestion in a mammal having GI tract inflammation comprising an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids. Claim 2 requires the mammal to be a dog or a cat. Claim 3 requires the composition to be administered in the diet of a dog or cat. Claim 5 requires the composition of claim 3 to contain fermentable in an amount of about 0.5 to 20% wt of the diet. Claim 7 requires the composition of claim 3 to contain omega-3 fatty acids in an amount of about 0.1 to about 3% wt. Claim 14 is directed to a method for managing diarrhea in a mammal having a GI tract inflammation, comprising orally administering to the said mammal a composition of an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids.

Shields, Jr. et al teach a dog food composition, comprising antioxidants, omega-3 fatty acids, and fermentable fiber (See col. 5, ln 61- col. 6, ln 23 & col. 6, ln 41-52). Shields, Jr. et al further specialize this generic composition for specific breeds/types of dogs, and their individual requirements and needs. The 'Herding Diet' comprises rice fruit and vegetable fibers, which provide fermentable fibers as well as antioxidants (See col. 11, ln 25-38 & col. 23, ln 4-14), omega-3 fatty acids (See col. 9, ln 48-51 & col. 11, ln 53-54), and glutamine (See col. 12, ln 11-15) (Claims 1-3). The composition is intended to be fed as the main diet of dogs in this 'Herding Group' (Claims 2-3). In particular, the diet contains a max of 4.0% fiber and 0.2% minimum of omega-3 fatty acids (See 'Analysis' col. 23); however the amount of fiber

Art Unit: 1651

can range from 0.5-10%, and the amount of omega-3 fatty acids can be from 1.1-5.6% (See col. 6, ln 24-29 & ln 49-52) (Claims 5 & 7). The 'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See col. 11, ln 18-28) (Claim 14).

Claims 1-3, & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (*In Practice*, 2002).

Applicant's claim 1 is directed to a composition suitable for mammalian ingestion in a mammal having GI tract inflammation comprising an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids. Claim 2 requires the mammal to be a dog or a cat. Claim 3 requires the composition to be administered in the diet of a dog or cat. Claim 14 is directed to a method for managing diarrhea in a mammal having a GI tract inflammation, comprising orally administering to the said mammal a composition of an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids.

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet which comprise fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine can benefit an animal with a stressed gastrointestinal tract (See Pg. 529, col. 2-Pg. 533, col. 1) (Claims 1-3). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See especially Pg. 533) (Claim 14). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1651

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089 (US 2002/082276 A1)), and Klimberg et al (*Arch Surg*, 1990).

Applicant's claim 1 is directed to a composition suitable for mammalian ingestion in a mammal having GI tract inflammation comprising an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids. Claim 2 requires the mammal to be a dog or a cat. Claim 3 requires the composition to be administered in the diet of a dog or cat. Claim 4 requires the composition of claim 3 to contain glutamine in an amount of about 0.1 to 5% wt. Claim 5 requires the composition of claim 3 to contain fermentable in an amount of about 0.5 to 20% wt of the diet. Claim 6 requires the composition of claim 3 to contain antioxidant in an amount of about 0.1 to 3% wt. Claim 7 requires the composition of claim 3 to contain omega-3 fatty acids in an amount of about 0.1 to about 3% wt. Claim 8 requires the composition of claim 4 to contain fermentable fibers in an amount of about 0.5 to 20% wt. Claim 9 requires the composition of claim 4 to contain the antioxidants in an amount of about 0.1 to 3% wt. Claim 10 requires the composition of claim 4 to contain omega-3 fatty acids in an amount of about 0.1 to 3% wt. Claim 11 requires the composition of claim 8 to contain antioxidants in an amount of about 0.1 to 3% wt. Claim 12 requires the composition of claim 8 to contain omega-3 fatty acids to in an amount of about 0.1 to 3% wt. Claim 13 requires the composition of claim 11 to contain omega-3 fatty acids in an amount of about 0.1 to 3% wt. Claim 14 is directed to a method for managing diarrhea in a mammal having a GI tract inflammation, comprising orally administering to the said mammal a composition of an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids.

Art Unit: 1651

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-3 fatty acids, in the amount of 0.2%; antioxidants; and glutamine (See col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis') (Claims 1-3, 5, 7, & 14). The 'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See col. 11, ln 18-28) (Claim 14). Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress (such as bouts of diarrhea). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animal's diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the diet in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells (See, e.g. Shields, Jr. et al, col. 12, ln 11-22) (Claims 4, 6, & 8-13). Though Klimberg et al uses rats as the

Art Unit: 1651

experimental animal, it would have been obvious to extend the results to include dogs, as described by Shields, Jr et al, because they are both mammals, both have simple digestive tracts, and it is known that glutamine has similar affects on both, it is simply the amount of glutamine that is extrapolated. For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al, to include cats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts would be obvious for cats as well as dogs.

Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals, and therefore their inclusion in the diet (col. 5, ln 65- col. 6, ln 11). Shields, Jr. et al, however, does not teach a specific amount of antioxidants present in the diet. Wadsworth et al also teach inclusion of vitamins and antioxidants, such as vitamins A and E, in amounts from 0-10% by weight (See col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without concern of over dosage. Therefore, though Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight (Claims 6, 9, 11, & 13).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice*, 2002).

Applicant's claim 1 is directed to a composition suitable for mammalian ingestion in a mammal having GI tract inflammation comprising an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids. Claim 2 requires the mammal to be a dog or a cat. Claim 3

Art Unit: 1651

requires the composition to be administered in the diet of a dog or cat. Claim 4 requires the composition of claim 3 to contain glutamine in an amount of about 0.1 to 5% wt. Claim 5 requires the composition of claim 3 to contain fermentable in an amount of about 0.5 to 20% wt of the diet. Claim 6 requires the composition of claim 3 to contain antioxidant in an amount of about 0.1 to 3% wt. Claim 7 requires the composition of claim 3 to contain omega-3 fatty acids in an amount of about 0.1 to about 3% wt. Claim 8 requires the composition of claim 4 to contain fermentable fibers in an amount of about 0.5 to 20% wt. Claim 9 requires the composition of claim 4 to contain the antioxidants in an amount of about 0.1 to 3% wt. Claim 10 requires the composition of claim 4 to contain omega-3 fatty acids in an amount of about 0.1 to 3% wt. Claim 11 requires the composition of claim 8 to contain antioxidants in an amount of about 0.1 to 3% wt. Claim 12 requires the composition of claim 8 to contain omega-3 fatty acids to in an amount of about 0.1 to 3% wt. Claim 13 requires the composition of claim 11 to contain omega-3 fatty acids in an amount of about 0.1 to 3% wt. Claim 14 is directed to a method for managing diarrhea in a mammal having a GI tract inflammation, comprising orally administering to the said mammal a composition of an anti-diarrhea effective amount of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids.

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Pg. 529, col. 2, and especially Pg. 533, col. 1) (Claims 1-3). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See especially Pg. 533) (Claim 14).

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega-3 fatty acids, and antioxidants, it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment

Art Unit: 1651

potential of the diet. Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would have been motivated to increase the amount of fermentable fiber, omega-3 fatty acids, and antioxidants, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega-3 fatty acids help to decrease inflammation, antioxidants promote immune response, and need to be replaced during bouts of diarrhea due to being flushed out, and glutamine has been found to provide energy for enterocytes during times of stress, boosting immune ability and GI health (See Chandler Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems (See Chandler Pg. 529, col. 2- Pg. 533, col. 1). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

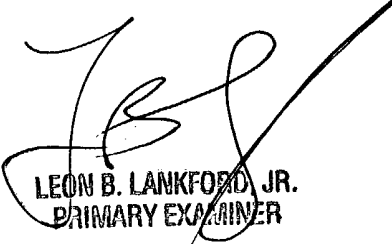
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651



LEON B. LANKFORD, JR.
PRIMARY EXAMINER